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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,476	02/21/2001	Ching Ming Chung	3669-0103P	6205

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/13/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,476

Applicant(s)

CHUNG ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 18 is/are rejected.
- 7) ☒ Claim(s) 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims 3-14 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 3-18 are pending and Claims 3-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1, and 15-18 are examined on merits.

Claim Rejections - 35 USC § 112

Claim 1 **remain rejected** for the reasons set forth at bottom half of page 3 to top half of page 4 of the previous Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of full scope of the claimed invention. Applicant states that the original claims 1 and 2 were rejected for recitation of functions and therefore applicant amended claim 1 to corresponding to original claim. However, the amended claim 1 is still drawn to a genus of DNA molecules that is differentially expressed in human hepatocellular carcinoma (HCC) or pancreatic adenocarcinoma. The specification provides evidence for only two DNA molecules, i.e. SEQ ID NO:1 and 3 which encode hcc-1 protein, and are expressed in HCC patients shown Figure 4. Based on these two DNA molecules, one cannot predict the types of additional DNA molecules, for example from allelic variance. Since the additional nucleic acid molecules include a large number of unpredictable nucleic acid molecules, possession of only two species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicants adequately describes SEQ ID NO:1 and 3.

Claim 1 (corresponding to original claim 2) **remain rejected** for the reasons set forth at bottom half of page 4 of the previous Office Action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 and 3, does not reasonably provide enablement for any other nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant argues that one in skilled in art would have no difficulty in determining whether a given nucleotide sequence has at least about 60% similarity to the cited sequence numbers and then it would be routine screening whether the sequence expresses an amount of mRNA. This argument is not persuasive because the claim is drawn to unknown biomarker nucleic acid molecules for pancreatic adenocarcinoma or hepatocellular carcinoma. Identification of a cancer biomarker is not trivial matter. In order to determine which other SEQ ID NO:1 or 3-related nucleic acid sequences are biomarker nucleic acid molecules for pancreatic adenocarcinoma or hepatocellular carcinoma, one in skilled has to identify which other nucleic acid molecules are differentially expressed in those cancer patients and this requires a large number of clinical samples and normal sex and age-matched control samples. Analysis of the large amount of clinical samples and comparing it with normal control require undue experimentation.

Claim Rejections - 35 USC § 102

Claim 1 **remain rejected** under 35 U.S.C. 102(b) as being anticipated by WO9845436-A2 (15 Oct. 1998).

Claim 1 is interpreted as drawn to any nucleotide sequence that hybridizes to SEQ ID NO:1 under the conditions specified in the instant claim. Applicant argues that WO9845436-A2 (Agonstino) only provides nucleic acid sequence that have a good match for the first 40% of hcc-1 and is far short of the 60% similarity required by the instantly claim 1. However the claim is not limited to 60% similarity to the entire SEQ ID NO:1. The claim could be also interpreted as drawn to any nucleotide sequence that hybridizes to SEQ ID NO:1 under the conditions specified in the instant claim.

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WO9845436-A2 teaches a nucleotide sequence that is 100 % identical from nucleotide 21 to 277 of SEQ ID NO:1 and the sequence that hybridizes to SEQ ID NO:1 under the conditions specified in the instant claim. Thus, WO9845436-A2 anticipates claim 1.

New Grounds of Rejection

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 is drawn to **nucleotide 286 through nucleotide 894 of SEQ ID NO:1**. Applicant is requested to point out the support for the limitation in the originally filed specification.

Allowable Subject Matter

Claims 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

December 4, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1602